Lilly

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Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1 - 23
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket No. 99N-4166
Agency Information Collection Activities: Proposed Collection; Comment Request; Electronic Records; Electronic Signature

Eli Lilly and Company (Lilly) offers the following comments in response to the above referenced Food and Drug Administration (FDA) Comment Request.

The docket document states that "The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records." In order to meet FDA's interpretations of required electronic records and electronic signatures activity requirements, we estimate that the documentation burden of such activity is significantly greater than the amount estimated in this docket document; we also project that while the proposal will perhaps reduce some documentation paperwork burden (which may or may not be "substantial") it will most certainly incur tremendous costs related to activity requirements for electronic records and signatures (21 CFR Part 11) that will outweigh any paperwork reduction benefits.

The estimate of paperwork reduction alone is not valid and fails to consider concurrent work burdens imposed, as described in the following text. Much of 21 CFR Part 11 relates to requirements for systems that contain electronic records regardless of whether or not there is any reduction in paperwork accompanying these systems. Part 11 establishes new requirements for electronic record systems, requirements that apply not only to future electronic record systems but also to those currently in use. These requirements include, but are not limited to: secure, computer-generated, time-stamped audit trails; electronic signatures on electronic records where a signature is required by regulation; and electronic archives. At a considerable expense, these requirements can be incorporated into new systems; however, it is extremely costly and inefficient to retrofit these requirements into present systems. For example, the cost to bring a chromatography system into compliance with Part 11 was estimated to be about $600,000 by our vendor. It is understood that this is an initial expense, however

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as changes are made to the system, the cost of maintenance increases because of these additional requirements. Commercial systems typically require an annual renewal fee of 30% of the original cost of the system to cover enhancements. This would place the annual maintenance costs just to support the Part 11 requirements for this chromatography system at $180,000. The cost, in money, manpower, and time, of modifying countless existing systems which a sponsor maintains to conduct and support clinical and laboratory studies will almost certainly 'far outweigh any benefits gained by paperwork reduction associated with these new requirements.

We believe the overall cost of 21 CFR Part 11 to be greater than the cost of our YEAR 2000 initiative. Part 11 implementation costs could be expected to be as much as $150 million as an initial expense for our company and an ongoing annual maintenance cost of around $30 million, and this activity could also impose a total annual burden of about 500,000 person hours per year if one assumes full compliance with the interpretation of these requirements.

Lilly fully supports the use of electronic records and electronic signatures, but we believe the burden to industry is clearly greater than what is documented in this publication. We encourage FDA to work with industry toward a reasonable interpretation of 21 CFR Part 11 to minimize the resources that will be spent in areas that will not yield the projected benefits as estimated in the dockets document, and instead endeavor to promulgate standards which improve information validation and quality, which can be implemented without undue burden to sponsors or the agency.

Sincerely,

ELI LILLY AND COMPANY

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cc: Janet Woodcock, M.D.